

SM.

Notice of Allowability

Application No.

09/439,594

Examiner

Joyce Tung

Applicant(s)

RABBANI ET AL.

Art Unit

1637

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address--

All claims being allowable, PROSECUTION ON THE MERITS IS (OR REMAINS) CLOSED in this application. If not included herewith (or previously mailed), a Notice of Allowance (PTOL-85) or other appropriate communication will be mailed in due course. **THIS NOTICE OF ALLOWABILITY IS NOT A GRANT OF PATENT RIGHTS.** This application is subject to withdrawal from issue at the initiative of the Office or upon petition by the applicant. See 37 CFR 1.313 and MPEP 1308.

1. ☒ This communication is responsive to 9/16/2003.
2. ☒ The allowed claim(s) is/are 146-200 (final claims 1-55).
3. ☒ The drawings filed on 01 October 2003 are accepted by the Examiner.
4. ☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).
 - a) ☐ All b) ☐ Some* c) ☐ None of the:
 1. ☐ Certified copies of the priority documents have been received.
 2. ☐ Certified copies of the priority documents have been received in Application No. _____.
 3. ☐ Copies of the certified copies of the priority documents have been received in this national stage application from the International Bureau (PCT Rule 17.2(a)).
 - * Certified copies not received: _____.
5. ☐ Acknowledgment is made of a claim for domestic priority under 35 U.S.C. § 119(e) (to a provisional application) since a specific reference was included in the first sentence of the specification or in an Application Data Sheet. 37 CFR 1.78.
 - (a) ☐ The translation of the foreign language provisional application has been received.
6. ☒ Acknowledgment is made of a claim for domestic priority under 35 U.S.C. §§ 120 and/or 121 since a specific reference was included in the first sentence of the specification or in an Application Data Sheet. 37 CFR 1.78.

Applicant has THREE MONTHS FROM THE "MAILING DATE" of this communication to file a reply complying with the requirements noted below. Failure to timely comply will result in ABANDONMENT of this application. **THIS THREE-MONTH PERIOD IS NOT EXTENDABLE.**

7. ☐ A SUBSTITUTE OATH OR DECLARATION must be submitted. Note the attached EXAMINER'S AMENDMENT or NOTICE OF INFORMAL PATENT APPLICATION (PTO-152) which gives reason(s) why the oath or declaration is deficient.
8. ☐ CORRECTED DRAWINGS (as "replacement sheets") must be submitted.
 - (a) ☐ including changes required by the Notice of Draftsperson's Patent Drawing Review (PTO-948) attached
 - 1) ☐ hereto or 2) ☐ to Paper No. _____.
 - (b) ☐ including changes required by the proposed drawing correction filed _____, which has been approved by the Examiner.
 - (c) ☐ including changes required by the attached Examiner's Amendment / Comment or in the Office action of Paper No. _____.

Identifying indicia such as the application number (see 37 CFR 1.84(c)) should be written on the drawings in the front (not the back) of each sheet. Replacement sheet(s) should be labeled as such in the margin according to 37 CFR 1.121(d).

9. ☐ DEPOSIT OF and/or INFORMATION about the deposit of BIOLOGICAL MATERIAL must be submitted. Note the attached Examiner's comment regarding REQUIREMENT FOR THE DEPOSIT OF BIOLOGICAL MATERIAL.

Attachment(s)

- | | |
|---|---|
| 1 <input type="checkbox"/> Notice of References Cited (PTO-892) | 5 <input type="checkbox"/> Notice of Informal Patent Application (PTO-152) |
| 2 <input type="checkbox"/> Notice of Draftsperson's Patent Drawing Review (PTO-948) | 6 <input type="checkbox"/> Interview Summary (PTO-413), Paper No. _____. |
| 3 <input checked="" type="checkbox"/> Information Disclosure Statements (PTO-1449 or PTO/SB/08),
Paper No. <u>03272003</u> | 7 <input type="checkbox"/> Examiner's Amendment/Comment |
| 4 <input type="checkbox"/> Examiner's Comment Regarding Requirement for Deposit
of Biological Material | 8 <input checked="" type="checkbox"/> Examiner's Statement of Reasons for Allowance |
| | 9 <input type="checkbox"/> Other |


ETHAN WHISENANT
PRIMARY EXAMINER

REASONS FOR ALLOWANCE

Following entry the amendment filed 9/16/2003, the claims 146-200 are pending.

1. The following is an examiner's statement of reasons for allowance:

No prior art has been found teaching or suggesting the process for detecting the presence of a specific target nucleic acid sequence comprising providing initial primers or nucleic acid constructs comprising two segments (A) a first segment (I) being sufficiently complementary to a first portion of said specific nucleic acid sequence to bind to which provides for template-dependent extension, and (B) a second segment being (I) substantially non-identical to the first segment, (ii) substantially identical to a second portion of said specific nucleic acid sequence, (iii) which binds to complementary sequences that are synthesized by extension of the first segment of said first initial primers with said specific target nucleic acid as a template and wherein the absence of a denaturation step, the first initial primers or first nucleic acid construct participate in the formation of a stem-loop structure after said specific target nucleic acid sequence is used as a template for extension, incubating the specific nucleic acid sequence and the initial primers or the nucleic acid construct in the presence of substrate, buffer and template dependent polymerizing enzyme, self-annealing between said second segment of said first initial primer or first nucleic acid construct and a segment formed after target template dependent extension of the first segment of said first initial primer or the nucleic acid construct, separating said first segment of said first initial primer or the nucleic acid construct from said specific target nucleic acid sequence and detecting the presence of said stem-loop structures formed in the previous step.

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The closest prior art is the reference of Honeyman et al. (Am. J. Vet. Res. 1999, Vol. 60, pg. 734-737). Honeyman et al. disclose a method of snapback SSCP analysis for genotyping Golden Retrievers for the X-linked muscular dystrophy alleles (See pg. 734 column 1). The method involves a snapback primer (See pg. 735, column 1, first paragraph). Honeyman et al. do not disclose the snapback primer which has the same features as the claimed initial primer which function differently from the snapback primer of Honeyman et al.

Any comments considered necessary by applicant must be submitted no later than the payment of the issue fee and, to avoid processing delays, should preferably accompany the issue fee. Such submissions should be clearly labeled "Comments on Statement of Reasons for Allowance."

2. Any inquiry concerning this communication or earlier communications from the examiner should be directed to Joyce Tung whose telephone number is 703 (305) 7112. The examiner can normally be reached on Monday - Friday, 8:30-5:00.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Gary Benzion can be reached on 703 308 1119. The fax phone number for the organization where this application or proceeding is assigned is 703 (305) 3014.

Any inquiry of a general nature or relating to the status of this application or proceeding should be directed to the receptionist whose telephone number is 703 (308) 0196.



**ETHAN WHISENANT
PRIMARY EXAMINER**

Joyce Tung 3.1

December 4, 2003